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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,753	10/29/2001	Yasuhiro Sakai	3029-74	7298

7590 06/27/2005

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,753

Applicant(s)

SAKAI ET AL.

Examiner

Francisco C. Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22-27,30 and 31 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 30 and 31 is/are allowed.
6) ☒ Claim(s) 20,22-24,26 and 27 is/are rejected.
7) ☒ Claim(s) 25 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 25, 2005, has been entered.

Claims 20, 22-27, 30 and 31 are pending and are examined on the merits.

Election/Restrictions

Applicant's election of the species wherein the nitrite reducer is sulfamic acid, in Paper No. 5, filed June 9, 2003, is again acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Because a composition as recited in claim 20, comprising

(a) a polymethine dye,

(b) a nitrite reducer selected from the group consisting of sulfamic acid or isoascorbic acid, and

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(c) a buffer for maintaining an acidic pH, is considered free of the prior art, examination has been extended to other species within the Markush group now in amended claim 20.

Claim Rejections - 35 USC § 103

Claims 20, 22-24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizukami et al (EP 0 882 983 A2) in view of Anderson et al (U.S. Pat. 5,135,736).

Mizukami discloses processes whereby a reagent comprising a polymethine dye and a quaternary ammonium surfactant, at a pH ranging from 4.5 to 11, is used to differentially stain leukocytes. See pages 3 and 4. Mizukami differs from the claims failing to disclose the inclusion in the reagent of a substance capable of reducing nitrite ions.

However, Mizukami clearly discloses the desirability of using a buffer in the composition. See, e.g., page 4, lines 32-34, disclosing the use of various buffers, including the organic acid citric acid. Thus, one of ordinary skill in the art at the time of applicant's invention clearly would have recognized that the claim-recited compound glycine, also a well known organic acid known to be suitable for use as a buffer within the pH

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range (4.5 to 11), would have been suitable for use as a buffer in Mizukami's compositions.

For example, Anderson, at column 20, lines 22-49, clearly discloses the suitability of glycine as a buffer for use in the *in vitro* testing of cells, as in the dyeing process of Mizukami. Recognizing from Anderson the suitability of glycine as a buffer for the *in vitro* testing of cells, the artisan of ordinary skill would have been motivated to have included it in Mizukami's staining reagent as the buffering component. Thus, the artisan of ordinary skill would have been motivated to have included a compound which meets the claim limitations of being both a buffer for maintaining an acidic pH, and being a nitrite ion reducer. A holding of obviousness over the cited claims is therefore required.

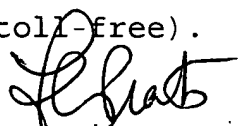
Claims 30 and 31 are allowed. Claim 25 is objected to as depending from a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Francisco C. Prats
Primary Examiner
Art Unit 1651

FCP